REMARKS

In the Office Action dated August 27, 2002, Examiner Epperson, the previous examiner, imposed a fifty-six-way (56) restriction requirement dividing the claims into 56 separate groups. According to Examiner Epperson, this multiple restriction requirement was required because there were multiple patentably distinct inventions.

Applicants are confused that 83 claims were separated into the 56 different groups, especially because applicants submitted a Preliminary Amendment when filing the present divisional application on October 2, 2000 (parent application U.S. Patent Application No. 09/220,415) that cancelled claims 1-39, 50-67 and 75-81. The only claims remaining in the application for examination include claims 40-49, 68-74 and 82-83. Thus understood, applicants will only address the claims that are currently pending in this divisional application.

The claims currently pending in this divisional application include: claims 40-41 and 82-83 that are compositions claims; claims 42-49 that recite methods of making the compositions; claims 68-73 that recite methods of treatment with the compositions; and claim 74 which is a method for screening for the compositions. All the claims are classified in class 514, subclass 2, thus the claims are not patentably distinct.

As stated by the current examiner, Examiner Stucker[1], during the examination of the parent application (U.S. Patent Application No. 09/220,415), the product claims and method of using the products "are not patentably distinct from each other because one having a method of using the instantly claimed peptides would obviously have to have the peptides to perform the method." The facts in this present application are analogous. The compositions are not patently distinct from the method of making and/or using the compositions because one would obviously have to have the compositions to performs the methods.

Moreover, in the parent application and the three corresponding divisional applications, multiple rejections for judicially created obviousness-type double patenting have been imposed further providing evidence that the compositions and methods of making and/or using the claimed compositions are not patentably distinct.

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[1] Examiner Stucker is also the Examiner on the three other divisional applications: U.S. Patent Application No. 09/676,739 (METHOD FOR TREATING HIV); U.S. Patent Application No. 09/675,776 (METHOD FOR PROMOTING HEMATOPOIESIS) and U.S. Patent Application No. 09/675,362 (METHOD FOR TREATING CANCER)

In view of the foregoing discussion, reconsideration for the withdrawal of the requirement for restriction is courteously requested. In the event the requirement is adhered to, applicants provisionally elect with traverse, the composition claims 40-41 (Group XXIII) and 82-83 (Groups (LIII and LIV), for further examination on the merits.

In accordance with Office guidelines recited in MPEP Section 821.04, when elected compositions claims 40-41 and 82-83 are found to recite patentable subject matter then all method claims for making and/or using the compositions of claims 40-41 and 82-83 may be rejoined and examined in this one application provided the method of making and using claims recite the product found to be patentable during examination of the elected invention. Thus understood, applicants request that when composition claims 40-41 and 82-83 are found to recite patentable subject matter, non-elected claims 42-47 and 68-74 should be taken up for examination.

Petition for Extension of Time/Fees Payable

The applicants hereby petition for a one (1) month extension of time, extending the deadline for responding to the August 27, 2002 Office Action from September 27, 2002 to October 27, 2002. The entry of this petition results in a petition fee of $55.00

A check in the amount of $55.00 is submitted herewith in payment of the petition fee for a one-month extension. The U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment, and to credit any excess payment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,

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APPENDIX A

In the specification

Please replace the text on page 1 following the title of the invention and before the "Field of Invention" with the following text so that the paragraphs read as follows:

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. Patent Application No. 09/220,415, filed December 24, 1998, which is in turn a continuation-in-part of the following applications, the entire disclosures of which are incorporated herein by reference:

PCT/US97/11210, entitled "Treatment and Prevention of Cancer by Administration of Derivatives of Human Chorionic Gonadotropin", filed on 24 June 1997[8] which is based on and claims priority to the priority following priority documents: U.S. Patent Application No. 08/669,676, filed June 24, 1996, now abandoned, and U.S. Patent Application No. 08/709,925, filed September 9, 1996, now U.S. Patent No. 5,997,871;

PCT/US97/11209, entitled "Methods of Promoting Hematopoiesis using Derivatives of Human Chorionic Gonadotropin", filed on 24 June 199[8]7, which is based on and claims priority to the priority following priority documents: U.S. Patent Application No. 08/669,654, filed June 24, 1996, now abandoned, and U.S. Patent Application No. 08/709,924, filed September 9, 1996, now U.S. Patent No. 5,968,513;

PCT/US97/11448 "Treatment and Prevention of Wasting Syndrome Based on Administration of Derivatives of Human Chorionic Gonadotropin", filed on 24 June 199[8]7, which is based on and claims priority to the priority following priority documents: U.S. Patent Application No. 08/669,675, filed June 24, 1996, now abandoned, and U.S. Patent Application No. 08/709,933, filed September 9, 1996, now abandoned; and

PCT/US97/11202, entitled "Treatment and Presentation of HIV Infection by Administration of Derivatives of Human Chronic Gonadotropin," filed on 24 June 199[8]7, which is based on and claims priority to the priority following priority documents: U.S. Patent Application No. 08/669,681, filed June 24, 1996, now abandoned, and U.S. Patent Application No. 08/709,948, filed September 9, 1996, now U.S. Patent No. 6,319,504.

APPENDIX B

All Pending Claims

40. A first composition comprising one or more first components of a second composition comprising a sample of native hCG or native β-hCG, the first components being separated from other components of the hCG or β-hCG sample, the native hCG or β-hCG sample not being purified to homogeneity in the second composition, the first components and the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoietic effects.

41. The first composition of claim 40 wherein the first components have an approximate apparent molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the apparent molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

42. A first composition produced by a process comprising the following steps:

a) subjecting a second composition comprising native hCG or native β-hCG to a size fractionation procedure, the native hCG or native β-hCG not being purified to homogeneity in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects; and

b) recovering fractions having such effects.

43. The first composition of claim 42 wherein the recovered fractions contain material having an approximate apparent molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the apparent molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

44. The first composition of claim 42, wherein the second composition is early pregnancy urine.

45. A method for producing a first composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects, said method comprising:

a) subjecting a second composition comprising native hCG or native β-hCG to a size fractionation procedure, the native hCG or native β-hCG not being purified to homogeneity in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoietic effects; and

b) recovering fractions active to inhibit HIV infection or replication or Kaposi's sarcoma or having pro-hematopoietic effects.

46. The method of claim 45 wherein the size fractionation procedure comprises the steps:

a) loading the second composition onto a gel filtration sizing column in a first buffer of 30 mM sodium phosphate, pH 8.3;

b) eluting components of the second composition from the column with second buffer of 30 mM sodium phosphate, pH 7.0 and 2 M sodium chloride; and

c) recovering fractions of the second composition having been eluted from the column.

47. The method of claim 45 wherein the gel filtration sizing column is a SUPERDEX 200™ column and wherein the recovered fractions contain material having an approximate apparent molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the apparent molecular weight is determined by elution from the SUPERDEX 200™ column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

48. The method of claim 47 wherein the second composition is early pregnancy urine.

49. The method of claim 48 wherein prior to subjecting the second composition to a size fractionation procedure, the second composition is subjected to the following steps:

a) adjusting the pH of the urine to a pH of approximately 7.2 causing the formation of a precipitate;

b) removing the precipitate from the urine;

c) concentrating the urine;

d) removing salt and lipid from the urine; and

e) lyophilizing the urine.

68. A method of treating or preventing a condition selected from the group consisting of HIV infection, cancer, wasting, and hematopoetic deficiency, in a human subject in need of such treatment or prevention comprising administering to the subject an amount of the first composition a therapeutically or preventatively effective amount of a first composition comprising one or more first components of a second composition comprising a sample of native hCG or native β-hCG, the first components being separated from other components of the hCG or β-hCG sample, the native hCG or β-hCG sample not being purified to homogeneity in the second composition, the first components and the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoietic effects.

69. The method of claim 68 wherein the first components have an approximate apparent molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD.

70. The method of claim 69, wherein the apparent molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

71. A method of treating or preventing a condition selected from the group consisting of HIV infection, cancer, wasting, and hematopoetic deficiency, in a human subject in need of such treatment or prevention comprising administering to the subject an amount of a first composition effective to treat or prevent HIV infection, the first composition being produced by a process comprising the following steps:

a) subjecting a second composition comprising native hCG or native β-hCG to a size fractionation procedure, the native hCG or native β-hCG not being purified to homogeneity in the second composition, the second composition having at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoietic effects; and

b) recovering fractions having such effects.

72. The method of claim 71 wherein the recovered fractions contain material having an approximate apparent molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD.

73. The method of claim 72 wherein the apparent molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β-hCG core protein or peptide, having a molecular weight of 10 kD.

74. A method of screening a preparation comprising hCG or β-hCG or a fraction of an hCG or β-hCG preparation or one or more portions of β-hCG for at least one therapeutic effect selected from the group consisting of anti-HIV effects, anti-cancer effects, anti-wasting effects, and pro-hematopoetic effects, comprising assaying the fraction for such effects.

82. A pharmaceutical composition comprising:
the first composition of claim 40; and
a pharmaceutically acceptable carrier.

83. A pharmaceutical composition comprising:
the protein or peptide of claim 42; and
a pharmaceutically acceptable carrier.